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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/666,403	09/17/2003	Karen Thecl	021756-002300US	8953
51206 7590 09/05/2007 TOWNSEND AND TOWNSEND AND CREW LLP TWO EMBARCADERO CENTER 8TH FLOOR SAN FRANCISCO, CA 94111-3834			EXAMINER HALE, ADAM G	
			ART UNIT 3609	PAPER NUMBER
			MAIL DATE 09/05/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/666,403

Applicant(s)

THEEL ET AL.

Examiner

Adam G. Hale

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_.

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 2, 4, 5, 8 – 15, 17, 18 and 21 – 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Stability Lab Information Manager (hereinafter referred to as "SLIM").

3. **With respect to claim 1**, SLIM discloses a computer implemented method for managing a stability study, comprising:

Generating one or more interfaces for the stability study, wherein the one or more interfaces define requirements for the stability study (interpreted to be disclosed by the Lab Work Request data entry forms, Page 4 Line 1)

Displaying the one or more interfaces (interpreted to be the displaying of the Lab Work Request data entry forms on screen, Page 4 Line 1)

Receiving input information for the one or more interfaces; the received input information for fulfilling the requirements (interpreted to be the feature of the Lab Work Request forms allowing the user to enter results, Page 4 Line 1)

Validating the received input information against business rules to determine if the input information is acceptable (interpreted to be the verification

of data entered into the Lab Work Request forms, Page 4 Line 1 and Page 5 line 4).

4. **With respect to claim 2** SLIM discloses:

if the input information is acceptable, storing the input information (interpreted to be inherently disclosed as the reference discloses the ability to enter data, from which reports are generated and the selected data from the reports may be saved, Page 4 Line 1 and Page 3 lines 9 – 10).

5. **With respect to claim 4** SLIM discloses:

determining if approval from a user is needed for the input information (interpreted to be the disclosure that data passes through a approval state, inherently disclosing a determination that approval from a user is necessary, Page 5 line 4).

6. **With respect to claim 5** SLIM discloses

receiving an indication of approval from the user; and storing the indication (interpreted to be the disclosure that data passes through a approval state, inherently disclosing receiving indication of the approval from the user, Page 5 line 4; storing the indication interpreted to be disclosed by the feature of all changes being event logged, Page 12 lines 2 – 4).

7. **With respect to claim 8** SLIM discloses

the one or more interfaces include an interface for a stage in a plurality of stages in the stability study (interpreted to be taught by the disclosure of the ability to add a test to a protocol, implying that a plurality of tests, i.e. stages, may be part of a protocol, i.e. stability study, Page 5 lines 2 – 3).

8. **With respect to claim 9** SLIM discloses

the plurality of stages comprise at least two of a stability study setup criteria, stability study planning criteria, initial sampling and testing criteria, stability study launch criteria, stability study testing criteria, and stability study evaluation criteria (interpreted to be the disclosure of assigning multiple storage dates for different storage conditions for a single study and calculation of number of units needed for each storage condition, Page 9 lines 2 – 3; and the creation of product-specific or test-specific schedules, Page 10 line 1).

9. **With respect to claim 10** SLIM discloses

outputting information summarizing the stability study (interpreted to be the automatic and unattended HTML report generation, Page 3 line 3).

10. **With respect to claim 11** SLIM discloses

determining a result of the stability study (interpreted to be inherently disclosed as the reference provides for data results to be subject to change by a

user, and hence a determination of the result of the stability study must occur,

Page 12 lines 3 – 4).

**11. With respect to claim 12 SLIM discloses**

the result is inputted by a user (interpreted to be the disclosure that data results may be changed, Page 12 lines 3 – 4).

**12. With respect to claim 13 SLIM discloses**

Determining a criterion in a plurality of criteria needed to complete the stability study (interpreted to be inherently disclose for the operation of the Lab Work Request data entry forms, Page 4 Line 1)

Outputting information for one or more requirements for the criterion (interpreted to be the displaying of the Lab Work Request data entry forms on screen, Page 4 Line 1)

Receiving information needed to complete the one or more requirements for the criterion based on the information outputted (interpreted to be the feature of the Lab Work Request forms allowing the user to enter results, Page 4 Line 1)

Validating the received information to determine if the one or more requirements are satisfied (interpreted to be the verification of data entered into the Lab Work Request forms, Page 4 Line 1 and Page 5 line 4).

If the one or more requirements have been satisfied, repeating steps (a) – (e) for another criteria in the plurality of criteria until the plurality of criteria have

been completed (interpreted to be disclosed by the teaching of the ability to assign multiple storage dates for different storage conditions for a single study, Page 9 line 2).

**13. With respect to claim 14 SLIM discloses**

the plurality of criteria comprise at least two of a stability study setup criteria, stability study planning criteria, initial sampling and testing criteria, stability study launch criteria, stability study testing criteria, and stability study evaluation criteria (interpreted to be the disclosure of assigning multiple storage dates for different storage conditions for a single study and calculation of number of units needed for each storage condition, Page 9 lines 2 – 3; and the creation of product-specific or test-specific schedules, Page 10 line 1).

**14. With respect to claim 15 SLIM discloses**

storing the received information (interpreted to be inherently disclosed as the reference discloses the ability to enter data, from which reports are generated and the selected data from the reports may be saved, Page 4 Line 1 and Page 3 lines 9 – 10).

**15. With respect to claim 17 SLIM discloses**

determining if approval from a user is needed for the criterion (interpreted to be the disclosure that data passes through a approval state, inherently disclosing a determination that approval from a user is necessary, Page 5 line 4).

**16. With respect to claim 18 SLIM discloses**

receiving an indication of approval from the user; and storing the indication (interpreted to be the disclosure that data passes through a approval state, inherently disclosing receiving indication of the approval from the user, Page 5 line 4; storing the indication interpreted to be disclosed by the feature of all changes being event logged, Page 12 lines 2 – 4).

**17. With respect to claim 21 SLIM discloses**

storing at least a portion of the received information (interpreted to be inherently disclosed as the reference discloses the ability to enter data, from which reports are generated and the selected data from the reports may be saved, Page 4 Line 1 and Page 3 lines 9 – 10).

**18. With respect to claim 22 SLIM discloses**

outputting information summarizing the stability study (interpreted to be the automatic and unattended HTML report generation, Page 3 line 3).

**19. With respect to claim 23 SLIM discloses**



receiving specifications for establishing the stability study; and generating the plurality of criteria based on the specifications (interpreted to be disclosed by the Lab Work Request data entry forms, Page 4 Line 1)

**20. With respect to claim 24 SLIM discloses**

Validating the received input information comprises validating the received input information against business rules that define whether the input information is acceptable (interpreted to be the verification of data entered into the Lab Work Request forms, Page 4 Line 1 and Page 5 line 4).

**21. With respect to claim 25 SLIM discloses**

determining a result of the stability study (interpreted to be inherently disclosed as the reference provides for data results to be subject to change by a user, and hence a determination of the result of the stability study must occur, Page 12 lines 3 – 4).

**22. With respect to claim 26 SLIM discloses**

the result is inputted by a user (interpreted to be the disclosure that data results may be changed, Page 12 lines 3 – 4).

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***Claim Rejections - 35 USC § 103***

23. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

24. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

25. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

26. **Claims 3 and 16** are rejected under 35 U.S.C. 103(a) as being unpatentable over SLIM in view of Strong US 6167523. SLIM discloses determining if the

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requirements for the stability study have been completed (interpreted to be the disclosure of data passing through draft, entry, verification and approval states, Page 5 line 4). SLIM does not disclose if the requirements have not been completed, outputting and interface for additional input information for the requirements that have not been completed. Strong discloses a method where if the requirements have not been completed (interpreted to be the teaching of validation of data entered into a form, and if data is determined to be invalid, providing to the user a message identifying the specific fields that include invalid data, C3 lines 36 – 43), outputting an interface for additional input information for the requirements that have not been completed (interpreted to be the method of resubmission of data from the user after an error message is sent indicating invalid data, C10 lines 45 – 49). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have included the features of Strong and the method of SLIM in order to provide a more efficient computer implemented method to verify if the requirements for a stability study have been satisfied.

27. Claims 6, 7, 19 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over SLIM as applied to claims 1 and 13 in view of Hughes et al. US Pub. 20020133395 (hereinafter referred to as "Hughes").

28. **With respect to claims 6 and 19**, SLIM does not disclose wherein the indication comprises at least one of an electronic signature and captured signature. Hughes

discloses the use of an electronic signature to indicate approval by a user of data, and further discloses that electronic signature may include signature recognition, interpreted to be captured signature (Para 0059). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have included the features of indication of approval by means of electronic signature of Hughes with the method of SLIM in light of the requirements imposed by 21 CFR Part 11 in regards to the use of electronic signatures for verification of electronic records submitted to the Food and Drug Administration.

29. **With respect to claims 7 and 20**, SLIM discloses receiving an indication from the user of approval, and thereby inherently disapproval (interpreted to be inherently disclosed as the references provides for result entry, verification and approval, Page 4 line 1 and Page 5 lines 1 – 4). SLI M does not disclose determining requirements that need to be completed for approval; and outputting an interface needed to complete the determined requirements. Hughes discloses determining requirements that need to be completed for approval (interpreted to be the comments attached by the reviewer, Fig. 1 and Para 0059), outputting an interface needed to complete the determined requirements (interpreted to be the electronic approver screen 90 in Fig. 5 and described in Para 0059). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have included the method of determining requirements that need to be completed for approval and outputting an interface needed to complete the determined requirements as disclosed by Hughes in

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the computer implemented method of SLIM, for the advantage of providing a more efficient and computer implemented method of determining requirements needed for approval and outputting an interface to complete the determined requirements.

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**Conclusion**

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Zumatrix Matrix Stability Study Manager discloses a computer implemented method and system for management of stability studies.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Adam G. Hale whose telephone number is 571-270-3509. The examiner can normally be reached on Monday through Thursday 7:30 - 6:00 Eastern.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terrence Till can be reached on 571-272-1280. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
AGH  
8/30/07

  
Terrence R. Till  
Supervisory Patent Examiner